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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/214,277 | 03/01/99 | KAWADA | 32-248P |

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HM12/0606

| EXAMINER |
|--------------------|
| BALASUBRAMANIAN, V |

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1624 | 8 |

DATE MAILED: 06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|---|-------------------------------|--|
| Office Action Summary | Application No. 09/214,277 | Applicant(s) KAWADA ET AL. | |
| | Examiner Venkataraman Balasubramanian | Art Unit 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants' response filed on 11/17/2000 is made of record. Election of group I, claims 7-12 in paper # 7 is acknowledged. Applicants' request the amended claims 15-17 is noted. However, there appears to be confusion as to total number of originally presented claims. There are 1-17 claims in the case and according to applicants it should have been 1-25. As noted by the applicants, the confusion appears to be due to the fact the copy of translation of newly added claims 18-25 by an amendment under PCT article 34. Examiner noted that although the search report indicates the same there is no copy of the translation in the case. Examiner has no way of knowing the content of these claims. Applicants should note that the preliminary amendment filed on 12/31/98 was based on the presence of claims 18-25 in the case but it could not be entered as noted in the office action. Furthermore, applicants in paper # 7 have incorporated in newly amended claims the missing claims 18-25 but there are now two sets of claims, namely claims 26-30 of paper # 6 and 18-27 of paper # 7 in the case.

Examiner tried to reach counselor Marc Weiner but he was not available.

Since the subject matter of claims 18-27 were not considered in earlier restriction requirement, a revised restriction is set forth in writing. In response to this action, applicants are asked to provide a copy of the translation of newly added claims 18-25 by an amendment under PCT article 34 and cancel all earlier amendments and present a clean set of claims incorporated the subject matter of originally presented claims 1-25.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 7-14, 18-22, 25 drawn to compound of formula I and composition.

Group II, claim(s) 15-17 and 26-27, drawn to processes for making compound of formula I

Group III, claim(s) 1-6 and 23-24 drawn to what appears to be a immuno-suppressor of IgE

If group II is elected applicant should elect a specific process of claims 15-17.

If group III is elected applicants should elect species of the compound recited therein with support in the specification.

Applicants should note that claims 18-21 appears to be same as claims 7-12 and the process claims 25-27 appears to be same as process claims 15-17. A clarification is requested.

The inventions listed as Groups I, II and III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

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Where there is lack of unity the requirement for restriction is proper- See MPEP 803.02. In addition, MPEP permits one product, one process , one composition and one method of use in a single invention. See also Official Gazette, 1134 OG 194, Jan 7, 1992 which clearly shows US position as regards to PCT cases .

Group I and II are related as product and various processes for making compound of formula I or II". Process of making compound of formula I can be used to make compound of formula " and more than one process can give either of the two product. Hence each process is patentably distinct.

As for group III, it relates to composition for immunosuppression of IgE with indeterminate scope as it is not clear what compound is included or excluded. Furthermore, applicants would not acquiesce to obviousness type rejection of subject matter of Group I or II over prior art JP 525'45 et al. (provided by the applicant) which reads on group III.

A telephone call was made to Mr. Marc Weiner on 6/5/2001 to request an oral election to the above restriction requirement, but did not result in an election being made as Marc Weiner was not available. Hence the restriction is set forth in writing.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM.

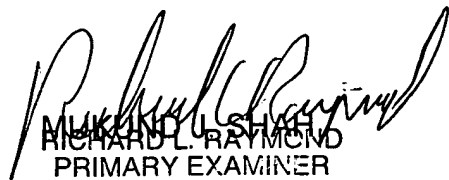
The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Vb

V. Balasubramanian (Bala)

6/2/2001


RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624
SUPERVISORY PATENT EXAMINER

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